Any development or acquisition of non–infringing products or technology or licenses could require the expenditure of substantial time and other resources and could have a material adverse effect on our business and financial results. If we are required to, but cannot, obtain a license to valid patent rights held by a third party, we would likely be prevented from commercializing the relevant product. We believe that it is unlikely that we would be able to obtain a license to any necessary patent rights controlled by companies, like Boston Scientific, against which we would compete directly. This would include, for example, a license to the Jang, Kunz, Hunter or Kinsella patents. If we need to redesign products to avoid third–party patents, we may suffer significant regulatory delays associated with conducting additional studies or submitting technical, manufacturing or other information related to the redesigned product and, ultimately, in obtaining approval.

In addition, some of our agreements, including our distribution agreements with Biotronik AG and the St. Jude Medical affiliates and our supply agreements for laser–cut stents and catheters, require us to indemnify the other party in certain circumstances where our products have been found to infringe a patent or other proprietary rights of others. An indemnification claim against us may require us to pay substantial sums to our supplier or distributors, including its attorneys' fees.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our market share, and, therefore, our revenues.

Our ability to protect our drug eluting stent technology from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our issued patents may not provide us with commercially meaningful protection for our drug eluting stents or afford us a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not issue from any pending or future patent applications owned by or licensed to us, and moreover, patents that have issued to us or may issue in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing stents like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references described or rendered obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the validity of our issued patents or the patentability of our pending patent applications. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in an interference, resulting in a loss of some portion or all of our U.S. position. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights, which may prompt our adversaries in such litigation to challenge the validity, scope or enforceability of our patents. If a court decides that our patents are not valid, not enforceable or of a limited scope, we will not have the right to stop others from using our inventions.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached, and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

There has been substantial litigation and other proceedings regarding patent and intellectual property rights in the medical device industry generally and the drug eluting stent industry in particular. We are currently defending, and may in the future be forced to defend, claims of infringement brought by our competitors and others, and we may institute litigation against others who we believe are infringing our intellectual property rights. The outcome of patent litigation is subject to substantial uncertainties, especially in medical device-related patent cases that may, for example, turn on the interpretation of claim language by the court which may not be to our advantage, and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in intellectual property litigation could result in significant expense. Some of our competitors, such as Boston Scientific, Johnson & Johnson and Guidant, have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from bringing our CoStar stent to market and achieving market acceptance. We, on the other hand, are a company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management's attention and quickly consume our financial resources.

If third parties file patent applications or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings with the U.S. Patent Office or in other proceedings outside the United States, including oppositions, to determine priority of invention or patentability. For example, we have filed an application seeking to provoke an interference with a patent owned by MicroCHIPS, Inc. with claims directed to an implantable stent having reservoirs and a system for releasing drugs contained in the reservoirs, as the priority date of the MicroCHIPS patent is after the priority date of our patent. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings.

Risks Related to Our Business

We will depend heavily on the success of our lead product candidate, our CoStar stent. If we are unable to commercialize our CoStar stent in major markets or experience significant delays in doing so, our ability to generate revenue will be significantly delayed and our business will be harmed.

We have invested all of our product development time and resources in our drug eluting stent technology, which we have commercialized initially in the form of our CoStar stent in certain countries in Asia and Latin America. We do not anticipate that the commercialization of our CoStar stent in these countries will provide us with significant revenues. We anticipate that in the near term our ability to generate meaningful revenues will depend solely on the receipt of regulatory approval and successful

commercialization of our CoStar stent in major markets. If we are not successful in the completion of clinical trials for the approval and commercialization of our CoStar stent, we may never generate any meaningful revenues and may be forced to cease operations. Although we are investigating the potential applicability of our stent technology to the treatment of an acute myocardial infarction, or AMI, we do not expect to seek regulatory approval of this product candidate for many years, if at all.

The commercial success of our CoStar stent will depend upon successful completion of clinical trials, manufacturing commercial supplies, obtaining marketing approval, successfully launching the product in major markets and acceptance of the product by the medical community and third-party payors as clinically useful, cost-effective and safe. If the data from our clinical trials is not satisfactory, we may not proceed with our planned filing of applications for regulatory approvals or we may be forced to delay the filings. Even if we file an application for approval with satisfactory clinical data, the FDA or foreign regulatory authorities may not accept our filing, or may request additional information, including data from additional clinical trials. The FDA or foreign regulatory authorities may also approve our CoStar stent for very limited purposes with many restrictions on its use, may delay approval, or ultimately, may not grant marketing approval for our CoStar stent. Even if we do receive FDA or foreign regulatory approval, we may be unable to gain market acceptance by the medical community and third-party payors.

We do not have the necessary regulatory approvals to market our CoStar stent or any other product candidates, and we may never obtain regulatory approval.

We do not have the necessary regulatory approvals to market our CoStar stent or any other product in the United States or in any foreign market. The regulatory approval process for our CoStar stent involves, among other things, successfully completing clinical trials and obtaining FDA approval of a premarket approval application, or PMA, and obtaining equivalent foreign market approvals, including taking the steps necessary for our CoStar stent to bear CE marking in the European Community. We cannot assure you that we will obtain the necessary regulatory approvals to market our CoStar stent in the United States or abroad. No regulatory approval is currently required to market our CoStar stent in the countries in which we are currently commercializing our CoStar stent. However, the Indian Ministry of Health has indicated that it will adopt a regulatory framework for medical devices in India. While Indian Ministry of Health officials continue to debate the framework to be adopted, our distributor's ability to commercialize the CoStar stent in India has been limited. We believe that receiving CE Mark for the CoStar stent may reduce these limitations. However, if we are required to obtain some form of license or regulatory approval in addition to CE Mark from Indian regulatory agencies, our distributor's ability to commercialize in India may be limited until such license or regulatory approval is obtained.

Our CoStar stent is a combination product that will be regulated primarily as a class III medical device in the United States, which cannot be commercially distributed until the FDA approves our PMA. The premarket approval process can be expensive and uncertain, requires detailed and comprehensive scientific and other data, generally takes several years and may never result in the FDA granting premarket approval. We will also have to obtain similar, or in some cases more stringent, foreign marketing approval in order to commercialize our product candidates outside of the United States. If we do not obtain the requisite regulatory or marketing approvals, we will be unable to market our CoStar stent and may never recover any of the substantial costs we have invested in the development of our CoStar stent.

If our pre-clinical tests or clinical trials for our CoStar stent or other product candidates do not meet safety or efficacy endpoints, our ability to commercialize our CoStar stent or other product candidates and our financial position will be substantially impaired.

Before marketing our CoStar stent or any other product candidate, we must successfully complete pre-clinical studies and clinical trials that demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical testing, is a long, expensive and uncertain process and is subject to delays. It may take us several years to complete our testing, if at all, and a clinical trial may fail at any stage. If our pre-clinical studies and clinical trials fail to demonstrate that our product candidates are safe and effective, our ability to commercialize our product candidates will be substantially impaired.

We have designed the protocol of our U.S. pivotal clinical trial for our CoStar stent based in part on prior clinical trials that used different stents. The results of these prior clinical trials may not be indicative of the clinical results we would obtain for our U.S. pivotal clinical trial.

Our clinical efforts are currently focused on the commercialization of our CoStar stent, which is a cobalt chromium, paclitaxel eluting stent. We have only limited clinical data on our CoStar stent, which we derived from the EuroSTAR and COSTAR I trials. Our other prior clinical trials used either a bare metal stainless steel stent or a stainless steel, paclitaxel eluting stent. In addition to using a different metal than used in our CoStar stent, the stainless steel stent had slightly different dimensions than our CoStar stent. We have designed the protocol, including the dosage formulations, for our U.S. pivotal clinical trial based on the results of these prior clinical trials. This trial has been designed in large part based on the results of our PISCES study, which used a stainless steel, paclitaxel eluting form of our stent technology, as well as on the results of our COSTAR I and EuroSTAR trials.

The results of these prior trials may not be indicative of the behavior of, and therefore the clinical results we will obtain with, our CoStar stent in our U.S. pivotal clinical trial. If results at least as favorable as the results observed in our prior trials are not observed in our U.S. pivotal clinical trial, our commercialization efforts will be delayed or halted and our business may be harmed.

The clinical results we have reported to date may not be indicative of future clinical results.

The clinical results that we have reported to date are limited to four- and twelve-month follow-up data from our PISCES study, six- and twelve-month follow-up data from the first arm of our EuroSTAR trial, six-month follow-up data from the second arm of our EuroSTAR trial and four- and twelve-month follow-up data from our COSTAR I trial. Our U.S. pivotal clinical trial, COSTAR II, will require at least eight-month follow-up data. While the stainless steel, paclitaxel eluting stent has shown favorable results after twelve months in our PISCES study and our CoStar stent has shown favorable results after twelve months in our COSTAR I trial and in the first arm of our EuroSTAR trial, it is possible that the long-term results we obtain with our CoStar stent in our U.S. pivotal clinical trial may not show similar effectiveness. In addition, any pre-clinical or clinical tests may fail to produce results satisfactory to the FDA or foreign regulatory authorities.

Our current and planned clinical trials may not begin on time, or at all, and may not be completed on schedule, or at all.

The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, place a clinical trial on hold, or do not permit us to expand the enrollment of a clinical trial;
- patients do not enroll in clinical trials at the rate we expect;
- patients are not followed-up at the rate we expect;
- clinical trial sites decide not to participate or cease participation in a clinical trial;
- clinical trial sites determine not to use or cease using the control stent;
- patients experience adverse side effects or events related to our products;
- patients die during a clinical trial for a variety of reasons, including the advanced stage of their disease and medical problems, which may not be related to our product candidates;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us not to be in compliance with regulatory requirements;

- third-party suppliers fail to provide us with critical components, including stent delivery catheters, cobalt chromium tubing and precision laser-cut stents, which conform to design and performance specifications;
- the failure of our manufacturing process to produce finished products which conform to design and performance specifications;
- changes in governmental regulations or administrative actions;
- the interim results of the clinical trial are inconclusive or negative;
- pre-clinical or clinical data is interpreted by third parties in different ways; or
- our trial design, although approved, is inadequate to demonstrate safety and/or efficacy.

Before we were able to commence enrollment in our U.S. pivotal clinical trial for our CoStar stent, we were required to file an investigational device exemption, or IDE, application with the FDA. Although we have received conditional approval of our IDE application from the FDA, the FDA's conditional approval of our IDE application allows us to begin only a limited enrollment in our COSTAR II trial. We are required to provide additional information to the FDA prior to the FDA granting full approval of our IDE application, including information that will be reviewed prior to the FDA approving full enrollment in our COSTAR II trial. While we anticipate that we will be able to provide the additional information that the FDA has requested, there can be no assurance that we will receive full approval of our IDE application on a timely basis, if at all. If we are unable to provide the additional information to the FDA, or if the FDA does not believe that the additional information we provide is sufficient, the FDA may require us to cease enrollment in the trial until adequate information is provided.

Clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. For example, our U.S. pivotal clinical trial for our CoStar stent is designed to enroll approximately 1,700 patients at up to 75 U.S. sites and 15 international sites. Patient enrollment in clinical trials and completion of patient follow-up in clinical trials depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures to assess the safety and effectiveness of our CoStar stent, or they may be persuaded to participate in contemporaneous trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical effects unrelated to our CoStar stent. Delays in patient enrollment or failure of patients to continue to participate in a study may cause an increase in costs and delays or result in the failure of the trial.

Our clinical trial costs will increase if we have material delays in our clinical trials or if we need to perform more or larger clinical trials than planned. Adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel the entire program.

Problems with the stent to be used in the control group could adversely affect our U.S. pivotal clinical trial for our CoStar stent.

Our U.S. pivotal clinical trial of our CoStar stent could be significantly delayed or harmed if we experience problems with the stent to be used in the control group for this trial. We plan to use Boston Scientific's TAXUS™ Express$^{2™}$ stent as the control stent in our U.S. pivotal clinical trial. In July 2004, Boston Scientific announced the recall of approximately 85,000 TAXUS™ Express$^{2™}$ stent systems and approximately 11,000 Express$^{2™}$ stent systems due to characteristics in the delivery catheters that have the potential to impede balloon deflation during a coronary angioplasty procedure. In August 2004, Boston Scientific announced that it would recall an additional 3,000 TAXUS™ Express$^{2™}$ stents. If during the enrollment and treatment period for our U.S. pivotal clinical trial, there is a recall of the control stent or the control stent is removed from the market, our trial would likely be substantially delayed. In addition, if certain sites decide not to participate or to cease participation in the trial because of a determination not to use the control stent, our U.S. pivotal clinical trial may be delayed. The FDA could also require us to redesign the trial based on an alternative control stent. Any significant delay or redesign would significantly delay and potentially impair our ability to commercialize our CoStar stent in the U.S.

We may not be successful in our efforts to expand our portfolio of products and develop additional drug delivery technologies.

A key element of our strategy is to discover, develop and commercialize a portfolio of new products in addition to our CoStar stent. We are seeking to do so through our internal research programs and intend to explore strategic collaborations for the development of new products utilizing our stent technology. Research programs to identify new disease targets, product candidates and delivery techniques require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- our delivery technologies may not safely or efficiently deliver the drugs; and
- product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective.

Our strategy also includes exploring the use of compounds and drugs other than paclitaxel for the treatment of restenosis and other indications. We may not be able obtain any necessary licenses to promising compounds or drugs on reasonable terms, if at all. In addition, our strategy includes substantial reliance on strategic collaborations with others to develop new products. If these collaborators do not prioritize and commit substantial resources to these collaborations, or if we are unable to secure successful collaborations on acceptable business terms, we may be unable to discover suitable potential product candidates or develop additional delivery technologies and our business prospects will suffer.

Pre-clinical development is a long, expensive and uncertain process, and we may terminate one or more of our pre-clinical development programs.

We may determine that certain pre-clinical product candidates or programs do not have sufficient potential to warrant the allocation of resources, such as the potential development of our stent technology for the treatment of AMI. Accordingly, we may elect to terminate our programs for such product candidates. If we terminate a pre-clinical program in which we have invested significant resources, our prospects will suffer, as we will have expended resources on a program that will not provide a return on our investment and will have missed the opportunity to have allocated those resources to potentially more productive uses.

We depend on single source suppliers for our CoStar stent components and the manufacturing components used in our CoStar stent. The loss of these suppliers could delay our clinical trials or prevent or delay commercialization of our CoStar stent.

We rely on third parties to supply us with the critical components used in our CoStar stent. Phytogen International LLC, which had been our sole supplier of paclitaxel, is operating under Canadian bankruptcy protection. If we are unable to obtain paclitaxel from Phytogen as a result of the bankruptcy proceedings, or for any other reason, or if Phytogen's supplies do not meet quality or other specifications, the commercialization of our CoStar stent could be prevented or delayed. We have obtained paclitaxel from another qualified supplier, but we have not yet used it for commercial production. If we obtain market approval for our CoStar stent, we anticipate that we will require substantially larger quantities of paclitaxel. Our suppliers my not provide us with sufficient quantities of paclitaxel that meet quality and other specifications, and we may not be able to locate alternative suppliers of paclitaxel in a timely manner or on commercially reasonable terms, if at all.

We do not have long-term contracts with our third-party suppliers of stent delivery catheters, polymers or the cobalt chromium tubing and laser-precision cutting process required to produce our CoStar stent. In addition, we do not have long-term contracts with our third-party suppliers of some of the equipment and components that are used in our manufacturing process. Except for the suppliers of our laser-cut stents and stent delivery catheters, none of our suppliers have agreed to maintain a guaranteed level of production capacity. Furthermore, suppliers that have guaranteed a level of production capacity may still be unable to satisfy our supply needs. Establishing additional or replacement suppliers for these components may take a substantial amount of time. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and U.S. import and customs regulations, which complicate and could delay shipments to us. Some of the manufacturers of stent components are also our competitors and may be reluctant to supply components to us on favorable terms, if at all.

Replacing suppliers could cause additional regulatory delays and the manufacture and delivery of our CoStar stent could be interrupted for an extended period of time, which may delay completion of our clinical trials or commercialization of our CoStar stent. In addition, we will be required to obtain regulatory clearance from the FDA or foreign regulatory authorities to use different suppliers or components. As a result, regulatory approval of our CoStar stent may not be received on a timely basis or at all.

We have limited manufacturing resources and experience, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our CoStar stent for research and development purposes at our manufacturing facility in Menlo Park, California, and for commercial sale at our manufacturing facility in Athlone, Ireland. If there were a disruption to our existing manufacturing facilities, we would have no other means of manufacturing our CoStar stent until we were able to restore the manufacturing capability at our current facilities or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our CoStar stent for use in our current and planned clinical trials or for commercialization, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

In order to produce our CoStar stent in the quantities that we anticipate will be required to meet our distributors' forecasts, we have increased, or "scaled up," the production process by a significant factor over the previous level of production. If the scaled−up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. In addition, if we obtain regulatory approval for our CoStar stent and are unable to manufacture sufficient quantities of our CoStar stent to meet market demand, our revenues, business and financial prospects would be adversely affected.

In addition, while we have validated our manufacturing process for consistency, we experience variability within and between manufacturing lots. Manufacturing lot variability may result in unfavorable clinical results.

Additionally, any damage to or destruction of our Menlo Park facilities or our equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce our CoStar stents. For example, because our Menlo Park facilities are located in a seismic zone, we face the risk that an earthquake may damage our facilities and disrupt our operations.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve regulatory approval for these manufacturing facilities, our business and our results of operations would be harmed.

Completion of our clinical trials and commercialization of our product candidates require access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. While our manufacturing facility in Ireland has received the requisite foreign regulatory approval, the FDA must also approve the facilities that manufacture our products for U.S. commercial purposes, as well as the manufacturing processes and specifications for the product. Suppliers of components of, and products used to manufacture, our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. Our suppliers may not satisfy these requirements. If we or our suppliers do not achieve required regulatory approval for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations. In addition, from time to time, suppliers are required to provide information to, and answer questions of, the regulatory authorities. If our suppliers are unable to satisfactorily respond to the regulatory authorities' requests for information, we may experience delays in obtaining, or may not obtain, regulatory approvals for our product candidates.

Quality issues in our manufacturing processes could delay our clinical trials and commercialization efforts.

The production of our CoStar stent must occur in a highly controlled, clean environment to minimize particles and other yield- and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are not able to maintain stringent quality controls, or if contamination problems arise, our clinical trials and commercialization efforts could be delayed, which would harm our business and our results of operations.

Our CoStar stent may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approval, our CoStar stent, or any other drug delivery device that we may develop, may not gain market acceptance among physicians, patients, health care payors and the medical community. The degree of market acceptance of any of our drug delivery devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If our CoStar stent, or any other drug delivery device that we may develop, is approved but does not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate meaningful product revenue and we may not become profitable.

If we fail to obtain an adequate level of reimbursement for our product candidates by third-party payors, there may be no commercially viable markets for our product candidates or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our product candidates. The efficacy, safety, performance and cost-effectiveness of our product candidates and of any competing products will determine the availability and level of reimbursement. If we are not able to obtain an adequate level of reimbursement for our product candidates by U.S. government sponsored healthcare or private insurance, the U.S. market may be much smaller than we expect. In

addition, reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought. Although we recently launched our CoStar stent in certain countries in Asia and Latin America, these countries do not currently have a reimbursement infrastructure, and we do not anticipate that the commercialization of our CoStar stent in these markets will provide us with significant revenues.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. In addition, third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our future revenues would be adversely affected.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to sell and market our CoStar stent, our business may be harmed.

We do not have a sales organization and have no experience as a company in the sales, marketing and distribution of drug eluting stents or other medical devices. To market and sell our CoStar stent internationally, we have entered into distribution agreements with third parties and anticipate that we will have to enter into additional distribution arrangements. Our existing distribution agreements are generally short-term in duration, and we will have to pursue alternative distributors if the other parties to these distribution agreements terminate or elect not to renew their agreements with us. If our relationships with our distributors do not progress as anticipated, or if their sales and marketing strategies fail to generate sales of our products in the future, our business, financial condition and results of operations would be harmed.

If our CoStar stent is approved for commercial sale in the United States, we currently plan to establish our own sales force to market it in the United States. If we develop our own marketing and sales capabilities, our sales force will be competing with the experienced and well-funded marketing and sales operations of our competitors. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. If we are unable to establish sales and marketing capabilities, we will need to contract with third parties to market and sell our CoStar stent in the United States. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product revenues could be lower than if we directly marketed and sold our CoStar stent, or any other drug delivery device that we may develop. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenues received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Some of our existing or future distributors may have products or product candidates that compete with ours, and they may have an incentive not to devote sufficient efforts to marketing our products. For example, Biotronik AG, with whom we have an agreement that primarily covers European distribution, is developing an absorbable magnesium alloy stent. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

The medical device industry is highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer and more effective than any products that we may develop, our commercial opportunity will be reduced or eliminated.

The medical device industry is highly competitive and subject to rapid and profound technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the drug delivery field.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions in the United States and abroad. Our principal competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. For example, Johnson & Johnson and Boston Scientific, two companies with far greater financial and marketing resources than we possess, have both developed, and are actively marketing, drug eluting stents which have been approved by the FDA. In addition, Medtronic Inc. recently announced that it received CE Mark approval for commercial sale of its Endeavor™ drug eluting coronary stent in European Community member countries. We may be unable to demonstrate that our CoStar stent offers any advantages over Johnson & Johnson's CYPHER™ stent, Boston Scientific's TAXUS™ Express²™ stent or Medtronic's Endeavor™ stent. In addition, in September 2005, Boston Scientific announced that it had received CE Mark approval for commercial sale of its Liberte™ paclitaxel eluting coronary stent system. Boston Scientific has stated that the TAXUS™ Liberte™ stent system is designed to further enhance deliverability and conformability, particularly in challenging lesions. Many other large companies, including Guidant Corporation and Abbott Laboratories, among others, are developing drug eluting stents. Guidant has announced that it has completed enrollment in its SPIRIT II and has enrolled more than 400 patients in its SPIRIT III clinical trials evaluating the safety and efficacy of its drug eluting stent system. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or mergers with or acquisitions by, large and established companies or through the development of novel products and technologies. For example, Biosensors International Group, Ltd. announced that its Netherlands-based subsidiary, Occam International B.V., received CE Mark approval for the Group's paclitaxel eluting stent, Axxion.

Our competitors may:

- develop and patent processes or products earlier than us;
- obtain regulatory approvals for competing products more rapidly than us; and
- develop more effective or less expensive products or technologies that render our technology or product candidates obsolete or non-competitive.

The industry in which we operate has undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances are made. Our competitors may develop and commercialize stents or other medical device or pharmaceutical products that are safer or more effective, have fewer side effects or are less expensive than any products that we may develop. For example, we are aware of companies that are developing various other less-invasive technologies for treating cardiovascular disease, which could make our stent platform obsolete. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If the third parties on whom we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct clinical trials for our product candidates, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to

assist with our pre-clinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates on a timely basis, if at all. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. For instance, one of our competitors is a major supplier of the intravascular ultrasound, or IVUS, catheters used in our clinical trials to measure percent volume obstruction, or the volume of the lumen, or the inner channel of the artery through which blood flows, in the stent occupied by restenotic tissue. If the supply of IVUS catheters to our clinical trial sites is interrupted, our clinical trials may be delayed or terminated.

Our product candidates are based on a new technology, and we have only limited experience in regulatory affairs, which may affect our ability or the time required to obtain necessary regulatory approvals, if at all.

Drug eluting stents were introduced in the U.S. marketplace in 2003. To date, the FDA has approved only Boston Scientific's TAXUS ™ Express^{2}™ and Johnson & Johnson's CYPHER™ drug eluting stents for commercial sale. Because drug eluting stents are relatively new, regulatory agencies, including the FDA, may be slower in evaluating product candidates. For example, there are currently several measures of restenosis, including binary restenosis rate, in-stent late loss, in-segment late loss, percentage volume obstruction and percentage diameter loss. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. It has not been settled which of these metrics, or another metric, is the ideal measure for evaluating the clinical effectiveness of stents. It is possible that a change in the accepted metrics may result in reconfiguration and delays in our clinical trials or our CoStar stent being considered not to be clinically effective.

Furthermore, unlike surface-coated stents, our product candidates are based on drug delivery polymer reservoirs and the use of a bioerodable polymer. Because there are currently no approved products based on this technology, the regulatory requirements governing this type of product may be more rigorous or less clearly established than those for already approved surface-coated stents or other vascular drug delivery devices. In addition, our CoStar stent has not been approved for use as a bare stent, and we do not expect to obtain FDA approval for this stent as a bare stent prior to filing our PMA with the FDA. We must provide the FDA and foreign regulatory authorities with pre-clinical and clinical data that demonstrate that our product candidates are safe and effective before they can be approved for commercial sale. We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical staff is limited. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals for our product candidates.

Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing problems or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products in major markets abroad.

We intend to market our products in international markets and recently began commercializing our CoStar stent in certain countries in Asia and Latin America. Although no regulatory approval is currently required to market our CoStar stent in these countries, we must obtain regulatory approvals to market our products in the European Community and many other foreign jurisdictions. In addition, countries that do not currently require regulatory approval to market our products may in the future require regulatory approval. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have a limited operating history. As of September 30, 2005, we had an accumulated deficit of $82.6 million. We have incurred net losses in each year since our inception in 1999. We expect to continue to incur operating losses, in the aggregate and on a per share basis, for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, net current assets and working capital.

Because of the numerous risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all. To date, we have not generated significant product revenues and we do not expect to generate significant product revenues until we successfully obtain market approval for and begin selling our CoStar stent in the European Community, which we may not be able to do. We have financed our operations and internal growth primarily through private placements of equity securities and convertible promissory notes, as well as our initial public offering of our common stock. We have devoted substantially all of our efforts to research and development, including clinical trials and to commercialization of our CoStar stent.

We expect our research and development expenses to increase in connection with the conduct of our clinical trials. As a public company, our general and administrative and legal costs have increased due to the additional operational and regulatory burdens applicable to public companies. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes–Oxley Act of 2002 and related regulations implemented by the Securities and Exchange Commission and the National Association of Securities Dealers, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We are currently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from product development activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Moreover, subject to regulatory approval of any of our product candidates, we expect to incur sales and marketing and increased manufacturing expenses.

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We may need to raise substantial additional capital to:

- fund our operations and clinical trials;
- continue our research and development;
- scale up our manufacturing operations;
- defend, in litigation or otherwise, any claims that we infringe third–party patent or other intellectual property rights; and
- commercialize our product candidates in major markets, if any such product candidates receive regulatory approval for commercial sale.

We believe that our cash and cash equivalent balances, as well as the interest we earn on these balances and revenues from future product sales will be sufficient to meet our anticipated cash requirements through at least the first half of 2007. However, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the costs of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third–party patent or other intellectual property rights;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the costs of building commercial scale manufacturing capabilities;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- licensing technologies for future development;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may be required to liquidate some or all of our assets or delay, reduce

the scope of or eliminate some or all of our planned research, development and commercial activities, which could harm our business.

We depend on our officers, and if we are not able to retain them or recruit additional qualified personnel, our business will suffer.

We are highly dependent on our Chairman and Chief Executive Officer, Dr. Frank Litvack, our Chief Technology Officer, John F. Shanley, our Chief Operating Officer, Dr. Azin Parhizgar and our other officers. Due to the specialized knowledge each of our officers possesses with respect to interventional cardiology and our operations, the loss of service of any of our officers could delay or prevent the successful completion of our clinical trials and the commercialization of our CoStar stent. Each of our officers may terminate their employment without notice and without cause or good reason. We do not carry key person life insurance on our officers.

In addition, our growth will require hiring a significant number of qualified scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities particularly with respect to engineering, regulatory affairs and clinical. Our offices are located in the San Francisco Bay Area, where competition for personnel with healthcare industry skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

If we are unable to manage our expected growth, we may not be able to commercialize our product candidates, including our CoStar stent.

We expect to rapidly expand our operations and grow our research and development, product development and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on our management and operational and financial resources. In particular, the commencement of our U.S. pivotal clinical trial has consumed a significant portion of management's time and our financial resources, and we expect that our U.S. pivotal clinical trial will continue to consume a significant portion of management's time and our financial resources, particularly if the FDA approves full enrollment in our U.S. pivotal clinical trial. To manage any further growth and to commercialize our CoStar stent in major markets, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

Changes in foreign currency exchange rates may increase our expenses or reduce our revenues.

Our current distribution agreement with Biotronik AG provides for payments to us in euros. In addition, we have established a manufacturing facility in Ireland, for which we incur expenses, including construction expenses, rental payments and employee salaries, denominated in euros. Our contracts for conducting certain of our clinical trials in Europe are also denominated in euros. Accordingly, if the euro strengthens against the U.S. dollar, our expenses related to our foreign clinical trials and Ireland facilities will increase, and if the U.S. dollar strengthens against the euro, our payments from Biotronik, if any, will decrease.

We may become exposed to fluctuations in other foreign currencies in the future, and our exposure to foreign currency exchange rates may adversely affect our results of operations.

Risks Related to Our Industry

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the regulatory and healthcare systems in ways that could impact our

ability to sell our products profitably, if at all. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted. For example, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, has announced that during the 2005 fiscal year, it will review in–patient and out–patient claims involving arterial stent implantation to determine whether Medicare payments for these services were appropriate. A determination by the OIG that inappropriate billing of arterial stents to Medicare is widespread could lead to increased enforcement of Medicare requirements regarding their use. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain additional collaborators and market our products. We expect to experience pricing pressures in connection with the future sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by future healthcare reforms.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. We may be subject to product liability claims if our stents cause, or merely appear to have caused, an injury. Claims may be made by consumers, healthcare providers, third–party strategic collaborators or others selling our products. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. In addition, if any of our product candidates are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims against us even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedure and related processes to implant our coronary stents into patients. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our stents may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with cobalt chromium tubing for our stents, those that laser cut our stents or those that provide the polymer incorporated into our stents, may be the basis for a claim against us.

These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit clinical trial volunteers or result in reduced acceptance of our products in the market.

Our operations involve hazardous materials, and we must comply with environmental laws and regulations, which can be expensive.

Our research and development activities involve the controlled use of hazardous chemicals. Our operations also produce hazardous waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. We generally contract with third parties for the disposal of such substances. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations. We do not have any insurance for liabilities arising from hazardous materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulation may impair our research, development or production efforts.

Risks Related to Our Common Stock

Our internal control over financial reporting may not be effective, and our independent registered public accounting firm may not be able to certify as to the effectiveness of our internal control over financial reporting, which could have a material adverse effect on our stock price.

We are evaluating our internal control over financial reporting in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal control over financial reporting, as required by Section 404 of the Sarbanes–Oxley Act of 2002 and the rules and regulations of the SEC, which we collectively refer to as Section 404. We are currently in the process of evaluating our current systems and processes and implementing new systems and processes and conducting the testing required in an effort to comply with the management assessment and auditor certification requirements of Section 404, which will initially apply to us as of December 31, 2005. In the course of our ongoing Section 404 evaluation, we have identified and continue to identify areas of internal controls that may need improvement, and we have instituted and continue to institute remediation efforts where necessary. However, we are still in the evaluation process, and we may identify conditions that may result in significant deficiencies or material weaknesses in the future. If we determine that we do not have adequate internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on our assessment of, and on the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

Anti–takeover defenses that we have in place could prevent or frustrate attempts to change our direction or management.

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These provisions:

- establish a classified board of directors, so that not all members of our board may be elected at one time;
- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue a new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law generally prohibits us from engaging in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Table of Contents

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over our affairs.

Our executive officers, current directors and holders of five percent or more of our common stock, as of September 30, 2005, beneficially owned approximately 36.4% of our common stock. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for small healthcare companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid for our common stock.

There are many events that may influence the market price for our common stock, including:

- results of our clinical trials;
- developments or disputes concerning patents or other intellectual property rights;
- litigation developments, including developments in our patient litigations;
- competition in the drug eluting stent market;
- failure of any of our product candidates, if approved for commercial sale, to achieve commercial success;
- regulatory developments in the United States and foreign countries;
- ability to manufacture our products to commercial standards;
- public concern over our products;
- the departure of key personnel;
- future sales of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- investors' perceptions of us; and
- general economic, industry and market conditions.

In addition, from time to time, we publicly announce (including in this Quarterly Report on Form 10-Q) the estimated timing of the accomplishment of various clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones include the enrollment of patients in our clinical trials, the release of data from our clinical trials and other clinical and regulatory events, including the submission to the FDA of a PMA for our CoStar stent and the receipt of CE Mark. If we do not achieve our projected development goals in the time frames we announce and expect, our stock price may decline. A decline in the market price of our common stock could cause you to lose some or all of your investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management.

If there are substantial sales of our common stock, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of our common stock, the market price of our common stock could decline significantly. As of October 31, 2005, we had 33,672,487 outstanding shares of common stock. Of these shares, all of the 6,900,000 shares sold in our initial public offering were freely tradeable without restriction or further registration unless purchased by our affiliates. Of the remaining 26,772,487 shares of common stock outstanding as of October 31, 2005, 26,224,840 shares were

immediately eligible for sale in the public market, subject in some cases to the volume, manner of sale and other limitations under Rule 144 or Rule 701 and vesting in the case of early exercised options; and 547,647 shares will become eligible for sale in the public market under Rule 144 from time to time upon expiration of their respective holding periods.

We have filed a registration statement covering the shares of common stock that are authorized for issuance under our stock option plans and employee stock purchase plan, which can be freely sold in the public market upon issuance, subject to restrictions on our affiliates. In addition, certain holders of our common stock that are parties to our investor rights agreement have rights with respect to the registration of their shares of common stock with the Securities and Exchange Commission. If we register their shares of common stock, these holders can immediately sell their shares in the public market without restriction.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock or other securities, and we currently do not anticipate paying any cash dividends in the foreseeable future. Accordingly, our stockholders will not realize a return on their investment unless the trading price of our common stock appreciates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short−term investments in a variety of securities, including commercial paper, money market funds and corporate debt securities. Our cash and cash equivalents as of September 30, 2005 included liquid money market accounts. Due to the short−term nature of these investments, we believe that there is no material exposure to interest rate risk.

We have some obligations in foreign currencies, principally our distribution agreement with Biotronik AG, contracts for conducting clinical trials and our lease payment obligations in Ireland, which are denominated in euros. We do not currently use derivative financial instruments to mitigate this exposure. However, we do not expect fluctuations in foreign exchange rates to have a material impact on our financial condition or results of operations.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Based on their evaluation as of September 30, 2005, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a−15(e) and 15d−15(e) of the Securities Exchange Act of 1934, as amended) were effective to ensure, at the reasonable assurance level, that the information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Control over Financial Reporting. We are currently in the process of evaluating our current internal controls systems and processes, implementing new internal controls systems and processes and conducting the testing required in an effort to comply with the management assessment and auditor certification requirements of Section 404, which will initially apply to us as of December 31, 2005. In the course of this ongoing Section 404 evaluation, during the quarter ended September 30, 2005, we identified areas of internal controls that may need improvement, and we instituted remediation efforts where necessary. Changes in our internal control over financial reporting in connection with the implementation of new systems and processes and the remediation efforts are reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

During the three months ended September 30, 2005, there were no material developments in the litigation previously disclosed under Part II, Item 1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, filed with the SEC on May 16, 2005 and under Part I, Item 3 of our Annual Report on Form 10-K for the year ended December 31, 2004, filed with the SEC on March 31, 2005.

On November 8, 2005, Boston Scientific and Boston Scientific Scimed, Inc. (Scimed) initiated legal proceedings against us in the District Court for the District of Delaware seeking a judgment that our CoStar stent infringes U.S. Patent No. 5,922,021, one of the Jang patents assigned to Boston Scientific. In the suit, Boston Scientific and Scimed are also seeking orders, among other things, preventing us from commercializing our CoStar stent in the United States and requiring us to pay damages. We are unable to predict the outcome of these proceedings.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from the Sale of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-119174), that was declared effective by the Securities and Exchange Commission on December 13, 2004, and a Registration Statement on Form S-1 filed pursuant to Rule 462 (File No. 333-121224) on December 14, 2004, pursuant to which we and a selling stockholder sold all 6,900,000 shares of our common stock that were registered. We did not receive any portion of the $3.1 million in net proceeds received by the selling stockholder in the offering. Of the $78.1 million in net proceeds received by us in the offering, after deducting offering expenses and underwriting discounts and commissions:

- approximately $29.5 million was used to fund ongoing operations, including the development of our products and our clinical trials and research programs, and for working capital and general corporate purposes; and

- the remainder of the net proceeds from the offering, approximately $48.6 million, remains invested in liquid money market accounts.

The application of the net proceeds from our initial public offering as set forth above represents our best estimate and does not represent a material change from the use of proceeds as described in the prospectus for our initial public offering. No such payments were made to directors, officers or persons owning 10 percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service.

Item 6. Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2(3)	Form of Common Stock Certificate.
10.38(4)	Form of Executive Change of Control Severance Agreement, dated September 27, 2005, by and between the Registrant and each of Azin Parhizgar, Ph.D. and Michael Boennighausen.
10.39(4)	Letter agreement, dated September 27, 2005, by and between the Registrant and Frank Litvack, M.D.
10.40(4)	Chief Executive Change of Control and Severance Agreement, dated September 27, 2005, by and between the Registrant and Frank Litvack, M.D.

31.1	CEO Certification required by Rule 13a−14(a) or Rule 15d−14(a).
31.2	CFO Certification required by Rule 13a−14(a) or Rule 15d−14(a).
32.1(5)	Certification required by Rule 13a−14(b) or Rule 15d−14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).

(1) Filed as Exhibit 3.2 to the Registrant's registration statement on Form S−1 (No. 333−119174), filed with the SEC on September 22, 2004, as amended, and incorporated herein by reference.
(2) Filed as Exhibit 3.6 to the Registrant's registration statement on Form S−1 (No. 333−119174), filed with the SEC on September 22, 2004, as amended, and incorporated herein by reference.
(3) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S−1 (No. 333−119174), filed with the SEC on September 22, 2004, as amended, and incorporated herein by reference.
(4) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8−K (File No. 000−51066), filed with the SEC on September 30, 2005 and incorporated herein by reference.
(5) This certification accompanies the Form 10−Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10−Q), irrespective of any general incorporation language contained in such filing.

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CONOR MEDSYSTEMS, INC.

By: /s/ MICHAEL BOENNIGHAUSEN

Michael Boennighausen
Vice President, Finance and Administration and Chief Financial Officer
(Duly Authorized and Principal Financial and Accounting Officer)

Dated: November 14, 2005

EXHIBIT 31.1

CERTIFICATION

I, Frank Litvack M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Conor Medsystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2005

/s/ FRANK LITVACK, M.D.

Frank Litvack, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Michael Boennighausen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Conor Medsystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2005

/s/ MICHAEL BOENNIGHAUSEN

Michael Boennighausen
Vice President, Finance and Administration and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a−14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Frank Litvack, M.D., Chief Executive Officer of Conor Medsystems, Inc. (the "Company"), and Michael Boennighausen, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10−Q for the period ended September 30, 2005, and to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 14th day of November, 2005.

/s/ FRANK LITVACK, M.D

Frank Litvack, M.D.
Chief Executive Officer

/s/ MICHAEL BOENNIGHAUSEN

Michael Boennighausen
Chief Financial Officer